



# PROPOSED RULE MAKING

**CR-102 (June 2004)**

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health- Board of Pharmacy

- ☒ Preproposal Statement of Inquiry was filed as WSR 06-08-104, 06-23-079 ;  
or  
☐ Expedited Rule Making--Proposed notice was filed as WSR ; or  
☐ Proposal is exempt under RCW 34.05.310(4).

- ☒ Original Notice  
☐ Supplemental Notice to WSR  
☐ Continuance of WSR

**Title of rule and other identifying information: (Describe Subject)**

The Board of Pharmacy is proposing amendments to WAC 246-863-095 Pharmacists professional responsibilities, and a new section, WAC 246-869-010 Pharmacies responsibilities to promote patient safety and access to health care by emphasizing the professional responsibilities of pharmacists and pharmacies

**Hearing location(s):** Renton Community Center  
1715 Maple Valley Highway  
Renton, WA 98057

Date: 3/29/07 *DSF*  
03/29/30

Time: 9:15 AM**Submit written comments to:**

Name: Doreen E. Beebe  
Address: Department of Health  
Board of Pharmacy  
PO Box 47863  
Olympia WA 98504-7863  
Website: <http://www3.doh.wa.gov/policyreview/> 3/23/2007 *DSF*  
fax (360) 586-4359 by (date) 04/19/2007

**Assistance for persons with disabilities: Contact**

Doreen E. Beebe by 01/22/2007 3/21/2007  
TTY (800) 833-6388 or () 711 *DSF*

**Date of intended adoption:** 03/30/2007

(Note: This is NOT the effective date)

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:**

The proposed rules meet the goals and objectives of the statute by promoting patient safety and access to health care. The proposed rules provide clear expectations to assure patients have access to safe and appropriate medication therapy by eliminating barriers that would prevent patients from receiving timely access to their lawful prescribed or therapeutically equivalent drugs and devices.

**Reasons supporting proposal:**

The proposed rules are needed to minimize barriers to health care and to reduce risks for patients' health where there may be an emergent need for a prescribed drug or device. Pharmacy clients should receive appropriate drugs and treatments without fear of intimidation, discrimination, or interference by pharmacy staff. Rules are needed to clarify and enforce these requirements; guidance would not have the same effect nor be enforceable.

**Statutory authority for adoption:**

RCW 18.64.005, RCW 18.130.050

**Statute being implemented:**

RCW 18.64.005, RCW 18.130.180

**Is rule necessary because of a:**

Federal Law?

☐ Yes ☒ No

Federal Court Decision?

☐ Yes ☒ No

State Court Decision?

☐ Yes ☒ No

If yes, CITATION:

DATE 2/15/2007

NAME (type or print)

Lisa Salmi

SIGNATURE

**CODE REVISER USE ONLY**CODE REVISER USE ONLY  
STATE OF WASHINGTON  
FILED

FEB 20 2007

TIME

WSR

716  
07-05-055

AM

PM

TITLE  
Acting Executive Director

(COMPLETE REVERSE SIDE)

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:**

No comments or recommendations.

**Name of proponent: (person or organization)** Board of Pharmacy

- ☐ Private  
☐ Public  
☒ Governmental

**Name of agency personnel responsible for:**

Name	Office Location	Phone
Drafting..... Lisa Salmi	Board of Pharmacy, PO Box 47863, Olympia WA 98504-7863	(360) 236-4825
Implementation.... Lisa Salmi	Board of Pharmacy, PO Box 47863, Olympia WA 98504-7863	(360) 236-4825
Enforcement..... Lisa Salmi	Board of Pharmacy, PO Box 47863, Olympia WA 98504-7863	(360) 236-4825

**Has a small business economic impact statement been prepared under chapter 19.85 RCW?**

☒ Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name: Doreen E. Beebe

Address: Board of Pharmacy

PO Box 47863

Olympia WA 98504-7863

phone (360) 236-4834

fax (360) 586-4359

e-mail [doreen.beebe@doh.wa.gov](mailto:doreen.beebe@doh.wa.gov)

☐ No. Explain why no statement was prepared.

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: Doreen E. Beebe

Address: Board of Pharmacy

PO Box 47863

Olympia WA 98504-7863

phone (360) 236-4834

fax (360) 586-4359

e-mail [doreen.beebe@doh.wa.gov](mailto:doreen.beebe@doh.wa.gov)

☐ No: Please explain:

AMENDATORY SECTION (Amending WSR 96-02-005, filed 12/20/95, effective 1/20/96)

**WAC 246-863-095 Pharmacist's professional responsibilities.**

(1) A pharmacist's primary responsibility is to ensure patients receive safe and appropriate medication therapy.

(2) A pharmacist shall not delegate the following professional responsibilities:

(a) Receipt of a verbal prescription other than refill authorization from a prescriber.

(b) Consultation with the patient regarding the prescription, both prior to and after the prescription filling and/or regarding any information contained in a patient medication record system provided that this shall not (~~preclude a~~) prohibit pharmacy (~~assistant~~) ancillary personnel from providing to the patient or the patient's health care giver certain information where no professional judgment is required such as dates of refills or prescription price information.

(c) Consultation with the prescriber regarding the patient and the patient's prescription.

(d) Extemporaneous compounding of the prescription (~~provided that~~), however, bulk compounding from a formula and IV admixture products prepared in accordance with chapter 246-871 WAC may be performed by a (~~level A~~) pharmacy (~~assistant~~) technician when supervised by a pharmacist.

(e) Interpretation of data in a patient medication record system.

(f) Ultimate responsibility for all aspects of the completed prescription and assumption of the responsibility for the filled prescription, such as: Accuracy of drug, strength, labeling, proper container and other requirements.

(g) Dispense prescriptions to patient with proper patient information as required by WAC 246-869-220.

(h) Signing of the poison register and the Schedule V controlled substance registry book at the time of sale in accordance with RCW 69.38.030 and WAC 246-887-030 and any other item required by law, rule or regulation to be signed or initialed by a pharmacist.

(i) Professional communications with physicians, dentists, nurses and other health care practitioners.

(~~2~~) (j) Decision to not dispense lawfully prescribed drugs or devices or to not distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies.

(3) Utilizing personnel to assist the pharmacist.

(a) The responsible pharmacist manager shall retain all professional and personal responsibility for any assisted tasks

performed by personnel under his or her responsibility, as shall the pharmacy employing such personnel. The responsible pharmacist manager shall determine the extent to which personnel may be utilized to assist the pharmacist and shall assure that the pharmacist is fulfilling his or her supervisory and professional responsibilities.

(b) This does not preclude delegation to an intern or extern.

(4) It is considered unprofessional conduct for any person authorized to practice or assist in the practice of pharmacy to engage in any of the following:

- (a) Destroy unfilled lawful prescription;
- (b) Refuse to return unfilled lawful prescriptions;
- (c) Violate a patient's privacy;
- (d) Discriminate against patients or their agent in a manner prohibited by state or federal laws; and
- (e) Intimidate or harass a patient.

## NEW SECTION

**WAC 246-869-010 Pharmacies' responsibilities.** (1) Pharmacies have a duty to deliver lawfully prescribed drugs or devices to patients and to distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies, or provide a therapeutically equivalent drug or device in a timely manner consistent with reasonable expectations for filling the prescription, except for the following or substantially similar circumstances:

(a) Prescriptions containing an obvious or known error, inadequacies in the instructions, known contraindications, or incompatible prescriptions, or prescriptions requiring action in accordance with WAC 246-875-040.

(b) National or state emergencies or guidelines affecting availability, usage or supplies of drugs or devices;

(c) Lack of specialized equipment or expertise needed to safely produce, store, or dispense drugs or devices, such as certain drug compounding or storage for nuclear medicine;

(d) Potentially fraudulent prescriptions; or

(e) Unavailability of drug or device despite good faith compliance with WAC 246-869-150.

(2) Nothing in this section requires pharmacies to deliver a drug or device without payment of their usual and customary or contracted charge.

(3) If despite good faith compliance with WAC 246-869-150, the lawfully prescribed drug or device is not in stock, or the prescription cannot be filled pursuant to subsection (1)(a) of this section, the pharmacy shall provide the patient or agent a timely alternative for appropriate therapy which, consistent with customary pharmacy practice, may include obtaining the drug or device. These alternatives include but are not limited to:

(a) Contact the prescriber to address concerns such as those identified in subsection (1)(a) of this section or to obtain authorization to provide a therapeutically equivalent product;

(b) If requested by the patient or their agent, return unfilled lawful prescriptions to the patient or agent; or

(c) If requested by the patient or their agent, communicate or transmit, as permitted by law, the original prescription information to a pharmacy of the patient's choice that will fill the prescription in a timely manner.

(4) Engaging in or permitting any of the following shall constitute grounds for discipline or other enforcement actions:

(a) Destroy unfilled lawful prescription.

(b) Refuse to return unfilled lawful prescriptions.

(c) Violate a patient's privacy.

(d) Discriminate against patients or their agent in a manner

prohibited by state or federal laws.  
(e) Intimidate or harass a patient.

Small Business Economic Impact Statement  
for Rule Concerning  
Pharmacist's Professional Responsibilities, WAC 246-863-095  
& Pharmacies' Responsibilities, WAC 246-869-010

**1. Briefly describe the proposed rule.**

The Department of Health, Board of Pharmacy is proposing amendments to WAC 246-863-095 *Pharmacist's professional responsibilities*, and a new section, WAC 246-869-010 *Pharmacies' responsibilities* to promote patient safety and access to health care by emphasizing the professional responsibilities of pharmacists and pharmacies.

WAC 246-863-095

The proposed rule states that it is a pharmacist's primary responsibility to ensure patients receive safe and appropriate medication therapy.

The proposed rule:

- 1) Prohibits a pharmacist from delegating the decision to not dispense a lawful prescribed drug or devices to pharmacy support staff.
- 2) Provides grounds for discipline when a pharmacist, pharmacy intern, or pharmacy ancillary personnel engages in or permits the following conduct that is unprofessional.
  - (a) Destroy unfilled lawful prescription.
  - (b) Refuse to return unfilled lawful prescriptions.
  - (c) Violate a patient's privacy.
  - (d) Discriminate against patients or their agent in a manner prohibited by state or federal laws.
  - (e) Intimidate or harass a patient.

Please note that proposed amendments to WAC 246-863-095 are not analyzed within this Small Business Economic Impact Statement because the rule affects individual pharmacists, but does not create costs for businesses.

WAC 246-869-010

The proposed rule states that pharmacies have a duty to deliver/distribute lawful prescribed drugs and devices or provide a therapeutically equivalent drug or device to patients in a timely manner. The rule establishes requirements for a pharmacy to assure patients have access to lawfully prescribed and clinically safe medication therapy when a pharmacist cannot dispense.

The proposed rule:

- 1) Provides examples of circumstances when it may be appropriate for a pharmacy not to deliver/distribute lawful prescribed drugs, devices, or provide therapeutically equivalent drugs. The list is not inclusive but validates additional circumstances as substantially similar to those listed in the proposed rule. The circumstances listed include: national or state emergencies or guidelines affect the availability, usage or supply; potentially fraudulent prescriptions; lack of specialized equipment or expertise to safely produce, store or dispense a pharmaceutical; or when a pharmacy is not compensated for its usual and customary or contracted charge.



- 2) Requires pharmacies to provide patients with a timely alternative to appropriate therapy when the drug is not in stock because it is not customarily needed by the pharmacy's patients, or the drug is temporarily out-of-stock.

Proposed Rule Options for Out of Stock Drugs		
Contact prescriber for alternative drug therapy	Return prescription to patient	Refer patient to another pharmacy that will fill the prescription

- 3) Provides grounds for discipline when a pharmacy engages in or permits the following conduct that is unprofessional.
- (a) Destroy unfilled lawful prescription.
  - (b) Refuse to return unfilled lawful prescriptions.
  - (c) Violate a patient's privacy.
  - (d) Discriminate against patients or their agent in a manner prohibited by state or federal laws.
  - (e) Intimidate or harass a patient.

**2. Is a Small Business Economic Impact Statement (SBEIS) required for this rule?**

Yes, a Small Business Economic Impact Statement (SBEIS) is required because the proposed rule may impose more than minor costs on pharmacies. The report analyzes the probable compliance costs of the proposed rules and compares the cost of compliance for small businesses with the costs of compliance for large businesses.

**3. Which industries are affected by this rule?**

The proposed rule can be expected to affect businesses identified by the Standard Industrial Classification code 5912 for drug stores and proprietary stores that engage in the retail sale of prescription drugs, proprietary drugs, and nonprescription medicines and may also carry a number of related lines, such as cosmetics, toiletries, tobacco, and novelty merchandise. Small pharmacy businesses are those businesses with 50 or fewer employees.

**4. What are the costs of complying with this rule for small businesses (those with 50 or fewer employees) and for the largest 10% of businesses affected?**

Background

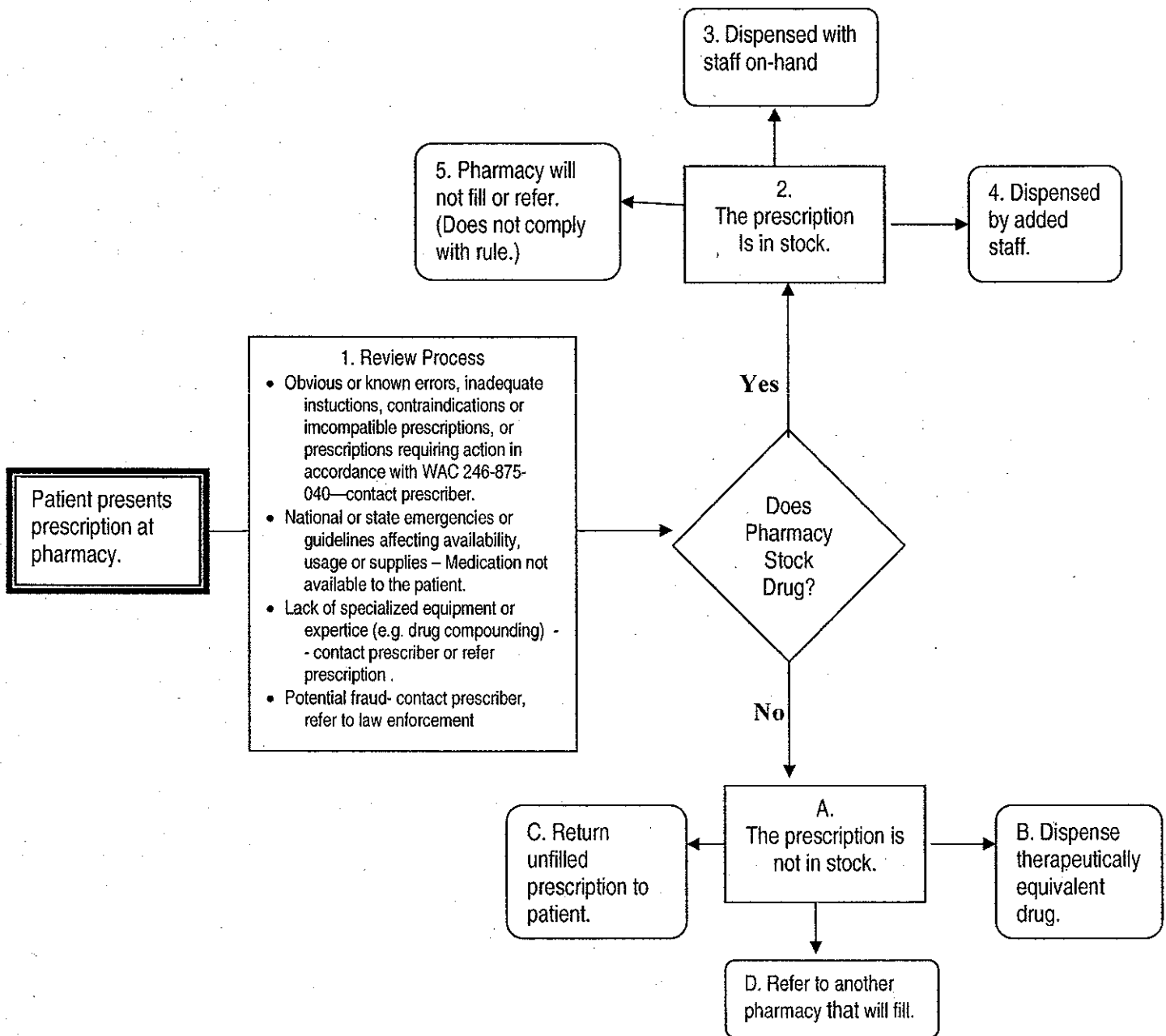
The Washington Board of Pharmacy (Board) is proposing adoption of rules amending Chapter 246-863 WAC -- Pharmacist's Professional Responsibilities and Chapter 246-869 WAC -- Pharmacy Licensing. The SBEIS will specifically address cost issues related to the adoption of amendments to Chapter 246-869 WAC. The statutes authorizing the Board to adopt the proposed rule amendments are RCW 18.64.005 and RCW 18.130.050.

The proposed amendment establishes requirements for pharmacies to deliver lawfully prescribed drugs and devices or provide a therapeutically equivalent drug to patients in a timely manner. The proposed rule will improve patient access to safe and appropriate health care by emphasizing the professional responsibilities of pharmacies.

Probable Costs of the Proposed Rules

To analyze the probable costs of the proposed rule, we must first look at the processes a pharmacy must follow in order to comply. Many of these steps are considered customary practice in a pharmacy and will not impose additional costs.

Diagram 1



The first scenario, captured in steps 2-5, illustrates the expectations provided in subsection 1 of the proposed rule, WAC 246-869-010. Compliance cost is defined as a loss in current revenue, a loss in assets, or higher operating costs.

- Step 1, the pharmacist conducts a professional review of the prescription to determine the appropriateness of filling the prescription.

- Step 3, after a thorough review of the prescription, the pharmacy delivers with staff on-hand. There is no compliance cost.
- Step 4, after a thorough review of the prescription, the pharmacy complies with the proposed rule by having additional staff available to ensure the patient is delivered the appropriate medication therapy in situations when another pharmacist objects. The probable cost of additional staffing falls mainly to community pharmacies (small businesses) compared to corporate/chain pharmacies (large businesses) simply because of the availability of additional pharmacists. Corporate pharmacies tend to deliver/dispense larger volumes of prescriptions that support multiple pharmacists on duty at one time or overlapping shifts. Chain pharmacies often use “floaters”, staff that can assist at various locations as needed. On the other hand, community pharmacies tend to have one pharmacist per shift and may have difficulty in finding part-time/on-call pharmacists.
- Step 5, the pharmacy is not in compliance with the proposed rule and may be subject to disciplinary actions.

Only Step 4 would result in costs to pharmacies. These costs are described in Table 4 and the narrative following that table.

The second scenario, captured in steps A – D, illustrates the expectations provided in subsection 3 of the proposed rule WAC 246-869-010. In this scenario, the medication/device inventory is established in compliance with WAC 246-869-150.

- Step B – After a thorough review of the prescription, the pharmacist contacts the prescriber to address concerns, when appropriate. In this situation, a therapeutically equivalent product is identified and dispensed.
- Step C & D – After a thorough review of the prescription, the pharmacist contacts the prescriber, when appropriate. In this situation, the pharmacy has determined that it is unable to provide a timely alternative for appropriate therapy. By request of the patient, the prescription is returned (step C) or the prescription is transferred to a pharmacy of the patient’s/agent’s choice that will fill the prescription in a timely manner (step D).

Note: Possible costs may be incurred by pharmacies to maintain a representative assortment of drugs in order to meet the pharmaceutical needs of its patients; however, these costs are already present under existing rules. In addition, costs for medications are passed onto the consumer and pharmacies have an array of options to manage medication inventories:

- Returning soon to expire medication inventory to wholesalers/manufacturers.
- More frequent pharmaceutical deliveries – up to 6 days a week – requiring less inventory on hand.
- Pharmacies commonly borrow medications from each other when needed.

Costs associated with subsection 4 of proposed rule WAC 246-869-010 would be incurred only by those pharmacies that violate this subsection. Pharmacies engaging in or permitting unprofessional conduct constitute grounds for discipline. The proposed rule defines this conduct as destroying or refusing to return unfilled lawful prescriptions; violating a patient’s privacy; harassing, intimidating or discriminating against a patient or their agent.

To assist in assessing the probable costs of the adoption of the proposed rule amendments, the Board surveyed a random selection of Washington pharmacies. The survey focused on current pharmacy practice and asked about the anticipated cost of complying with the proposed rule. Responses to the survey represented 39% of the 1370 pharmacies located in Washington State.

### Response to Survey by Pharmacy Type

Table 1

<b>Rural</b>	<b>Urban</b>	<b>Unknown</b>	<b>Retail Chain</b>	<b>Totals</b>
38	67	7	428	540

Note: We contacted the corporate offices of 9 retail chains, rather than the individual pharmacies within the chain, to get responses to the survey based on corporate standard policies and procedures. The 9 corporations represent 428 retail chain pharmacies. The 428 pharmacies are located in rural and urban areas.

To obtain information about compliance with the rule, the Board asked pharmacies specifically, "If a rule is adopted that required a pharmacy to dispense all lawful prescribed prescriptions, how might your pharmacy comply?" Although there is some resistance to the proposed rules the majority of pharmacies in each category indicated that they would comply with the rule

### Pharmacy Compliance with Proposed Rule

Table 2

<b>Number of pharmacies responding</b>	<b>Rural (38)</b>	<b>Urban (67)</b>	<b>Pharmacy Chains (9 corporations)</b>
Number and percent of pharmacies indicated that they be able to comply with the rule.	32 (84%)	62 (92%)	9 (100%)

The Board also asked what, if any, policies/procedures might currently be in place that would allow a pharmacy to provide services to patient if a pharmacist refuses to dispense a lawful prescription for moral, ethical or religious reasons. Table 2 shows that few pharmacies have policies and procedures in place to ensure that, when a pharmacist refuses to dispense, patients receive appropriate medication therapy in a timely manner.

### Pharmacist Refusal-Procedures

Table 3

<b>Number of pharmacies responding</b>	<b>Rural (38)</b>	<b>Urban (67)</b>	<b>Pharmacy Chains (9 corporations)</b>
Number and percent of pharmacies that currently have procedures in place if a pharmacist refuses to dispense.	3 (8%)	7 (10%)	5 (55%)

It is important to note that a small number of respondents did indicate that additional staffing would be necessary to ensure compliance with the rule.

**Probable Staffing Cost to Comply With Proposed Rule**  
**Table 4**

	<b>Rural (38)</b>	<b>Urban (67)</b>	<b>Chain Pharmacies (428) Representing 9 corporations</b>
Pharmacies indicating additional pharmacists needed.	1 pharmacy	6 pharmacies	2 corporations
Cost of additional pharmacists needed Based on \$80,000 per pharmacist.	\$80,000	\$80,000cost to most pharmacies replying*	\$14,194 average cost per pharmacy**
Pharmacies indicating a probable cost of less than \$1,000	1 pharmacy	7 pharmacies	0 corporations
Pharmacies indicating no additional cost	26 pharmacies	50 pharmacies	3 corporations
Pharmacies that did not answer the question.	10 pharmacies	4 pharmacies	4 corporations

\*5 pharmacies require 1 pharmacist at \$80,000 and 1 pharmacy reported needing 1.5 pharmacists (\$80,000) times 1.5 equals \$120,000.

\*\*11 pharmacists at \$80,000 are shared at 62 pharmacies: (\$880,000) divided by 62 equals a \$14,194 average per pharmacy.

Of the pharmacies surveyed, 87% anticipate no additional staffing costs. For the pharmacies that employ pharmacists that will not dispense certain drugs it is estimated that the added yearly staffing costs will average \$80,000 for small pharmacies and \$14,194 for chain store pharmacies (large businesses).

These assumptions illustrate the likelihood that the proposed rules may impose a disproportionate financial impact on small businesses. Many health care organizations and associations have reported a serious shortage of pharmacists for a number of years. The shortage can be attributed to growth in prescription volume and new employment opportunities for pharmacists.

Seventy-nine percent of community pharmacies responding to the survey rated the possibilities of finding an additional or temporary pharmacist as "very difficult" or "impossible". Sixty-seven percent of corporate retail chain pharmacies echoed these concerns.

However, as stated earlier in this analysis, the responsibilities established in the proposed rule mirror those processes that are customary practice in pharmacies today and would not result in additional costs. Additional pharmacist staffing costs and recruitment challenges pose real obstacles for any pharmacy that must institute alternatives to fulfilling its duty to deliver lawfully prescribed drugs and devices (as illustrated in step 4 in the diagram1).

#### Probable Benefits

The Board of Pharmacy has determined that the probable benefits of the proposed rules are greater than its probable costs to those that must comply. Costs of complying with the proposed rules must be balanced against the significant medical and social cost of not receiving a time-dependent medication in a timely manner. Access to medication is a critical factor in an individual's health and the efficacy of some medications is directly related to receiving the medication within a specified time.

Healthcare providers stress the importance of taking medication as prescribed. For example, when a patient has an infection they are instructed to take the entire supply of antibiotics prescribed. Compliance or adherence refers to their ability to take their medications as prescribed. People who comply have better results in combating diseases than those who do not.

For example, human immunodeficiency virus (HIV) medications are highly time sensitive. An HIV patient must regularly take the HIV drugs prescribed to suppress the virus. The consequences of missing as few as three dosages can result in the virus mutating. If the virus mutates the current drug regimen is no longer effective, requiring new tests to determine what new combination of drugs may be effective. New drugs are usually less effective and more expensive. Given that the mutation is permanent, the ultimate consequence is that the patient's probability of long term survivability can be greatly diminished.

Each time a HIV patient infection is prevented by treatment; there is a cost avoidance of \$303,000<sup>a</sup>. Healthcare providers caring for HIV patients refer to the "72 hour rule". When a patient misses medication doses, the drug levels fall and the virus is able to multiply. The "72 hours rule" refers to the time beyond which the virus can mutate and become resistant. If the patient has a gap in taking their medication longer than 72 hours, the provider must repeat expensive genotype and phenotype lab tests which cost from \$500-1000 each to establish whether treatment failure has occurred.<sup>b</sup>

HIV patients who develop viral resistance have to use what is called "salvage therapy". The medications used in salvage therapy have far greater side effects and one of the drugs used must be given by injection, at a cost of \$1500 to \$1800 each month. During this time the patient has an increased ability to transmit the HIV virus to others. The patient is also immunosuppressed and vulnerable to serious infections.

Emergency contraceptive pills would be another example of a time-dependent medication. In the U.S., about 50% of all pregnancies are unintended. This is the highest rate of all industrialized nations. If a woman receives emergency contraceptive pills within 72 hours of intercourse, there is a high probability of preventing pregnancy. Emergency contraceptive pills effectively prevent

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<sup>a</sup> JS Gallant. Moore News Quarterly vol 1 (1) December 2000.

<sup>b</sup> Richard Aleshire, DOH HIV Program, personal communication.

unintended pregnancy at a cost of \$35 - \$45. If barriers impede the timely administration of this contraception pregnancy is likely to occur. Unintended pregnancies have been shown to have significant quantitative and qualitative costs.<sup>c</sup>

When a woman has an unintended pregnancy, the impacts of an abortion may have serious emotional and health risks. The long term costs associated with unwanted pregnancies have been calculated to be in the hundreds of thousands of dollars. The costs can be thousands of times more expensive than the cost of the emergency contraceptive pills prescription.

A new analysis by the Guttmacher Institute, published in August 2006 as part of the Institute's *Occasional Report* series, looked at the expanding eligibility for Medicaid-covered contraceptive services as a potential way of reducing unplanned pregnancy and, thereby, abortion. The findings suggest that providing access to contraceptive services for all Medicaid-funded women would be very cost-effective program. This approach would avert \$2.3 billion in costs from unplanned births and results in a net savings of \$1.5 billion in Medicaid costs in the third year of the program's operation.<sup>d</sup>

A similar case can be made for other time-dependent medications or devices such as insulin and diabetic syringes, emergency contraceptive pills and erectile dysfunction medications.

#### **5. Does the rule impose a disproportionate impact on small businesses?**

Yes, the cost of additional staffing of rule compliance for community pharmacies that reported a need to hire staff to comply with the proposed rule is much greater than the average cost of additional staffing for corporate pharmacies that indicated a need to hire staff to comply. However, only one of 38 small rural pharmacies, and six of 67 small urban pharmacies indicated a need to hire an additional pharmacist in order to comply with the rule. More than two thirds of small rural and urban pharmacies surveyed said they would incur no costs of complying with the proposed rule.

#### **6. If the rule imposes a disproportionate impact on small businesses, what efforts were taken to reduce that impact (or why is it not "legal and feasible" to do so) by**

##### **a) reducing, modifying, or eliminating substantive regulatory requirements?**

Reducing, modifying, or eliminating substantive regulatory requirements is not legal or feasible because the proposed rule establishes a duty to dispense prescriptions as a universal requirement to the practice of pharmacy. Prescriptions that must be taken within a short timeframe by the patient need a timely response from the pharmacy to provide the medications. On the other hand, the rule reduces the impact by including customary pharmacy practices when the time-dependent medication is not in stock.

The pharmacist may call the prescriber for a therapeutically equivalent drug, return the prescription to the patient, or refer the patient to another pharmacy with the needed medication.

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<sup>c</sup> SK Henshaw. Unintended Pregnancy in the U.S. *Family Planning Perspectives*. 30(Jan-Feb)24-29, 1998

<sup>d</sup> The Guttmacher Institute. (2006) *U.S. Teenage Pregnancy Statistics National and State Trends and Trends by Race and Ethnicity*. New York: The Guttmacher Institute.

Many of the responding pharmacies, who don't stock the time-sensitive medication, indicated they have or will develop a referral system as the least costly alternative.

For those pharmacies who allow the right of refusal to their pharmacists, the least cost alternative is to have pharmacist coverage with on-call pharmacist, or in the case of the larger pharmacies having at least one pharmacist on duty that will dispense the medication.

**b) simplifying, reducing, or eliminating record keeping and reporting requirements?**

The board considered simplifying, reducing, or eliminating record keeping and reporting requirements as a means to reduce the impact of the rule on small businesses. Recordkeeping requirements for pharmacies are defined in federal and state laws. The board does not have the authority to change federal or state law.

**c) reducing the frequency of inspections?**

The adoption of the proposed rule does not impact the board's inspection process. Reducing inspections would not be a viable way of reducing costs to affected small businesses. Conducting inspections is necessary to protect public health and safety.

**d) delaying compliance timetables?**

The board has not considered delaying implementation of the rule to give affected businesses time to find ways they can comply. The intent of the rule is to require timely compliance by pharmacies and pharmacists in delivering/dispensing appropriate medication therapy to patients. Timeliness of medication delivery to the patient is the focus of proposed rules. To delay compliance with the proposed rules would not be in the best interest of the public.

**e) reducing or modifying fine schedules for noncompliance?**

Assuring timely access to medications is a critical factor in an individual's health. The efficacy of some medications is directly related to receiving the medication within a specified time. Reducing fines for small businesses who decide not to comply with the proposed rule does not meet the goal of the proposed rule.

**f) any other mitigation techniques?**

a) The rule applies to pharmacies, as well as pharmacists, to provide pharmacies with flexibility in staffing to meet the requirements of the proposed rule.

b) The rule excludes national or state emergencies affecting the availability or supplies of drugs and devices.

c) The proposed rule excludes specialized pharmacy practices that only provide limited prescriptions like compounded drugs or nuclear medicine drugs.

d) Within the 112 community pharmacies and 428 corporate pharmacies surveyed, 404 pharmacists have a collaborative drug therapy agreement. The agreements allow the pharmacists



to both prescribe and dispense medications in a timely manner, allowing even greater access to drugs or devices.

**7. How are small businesses involved in the development of this rule?**

Small pharmacies been involved in the development of this rule through stakeholder meetings, letters and messages sent to the Board of Pharmacy, representation on the Board, and participation in a pharmacy cost of rule survey sent to rural and urban pharmacies.